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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

#13
8-16-2

In re Application of:	Garibaldi et al.
Serial No.:	09/292,096
Filed:	April 14, 1999
For:	METHOD AND APPARATUS FOR MAGNETICALLY CONTROLLING ENDOSCOPES IN BODY LUMENS AND CAVITIES
Examiner:	J. Leubecker
Group Art Unit:	3739

Commissioner for Patents
Washington, D.C. 20321

APPLICANTS' BRIEF ON APPEAL

Pursuant to 37 C.F.R. § 1.192, Applicants submit their Brief on Appeal, as follows:

Real Party in Interest (37 C.F.R. § 1.192 (c)(1))

The real party in interest in this appeal is Stereotaxis, Inc., a Delaware corporation, having a place of business at 4041 Forest Park Avenue, St. Louis, MO 63136, by virtue of an assignment recorded July 23, 1999 at Reel 010112, Frame 0968.

Related Appeals and Interferences (37 C.F.R. §1.192(c)(2))

There are no other appeals or interferences known to Applicants, or to Applicants' legal representatives or assignees, which will directly affect, or would be directly affected by, or have a bearing on, the Board's decision in this appeal.

Status of the Claims (37 C.F.R. §1.192(c)(3))

Claims 2-39 are pending in this application. Claims 8 – 39 have been withdrawn from consideration. Claims 2 – 17 were finally rejected in the Office Action of November 29, 2001, and are the subject of this appeal.

Status of Amendments (37 C.F.R. §1.192(c)(4))

No amendments were filed after the final rejection of November 29, 2001.

Summary of Invention (37 C.F.R. §1.192(c)(5))

The claimed invention relates to an endoscope system and method for navigating an endoscope. The system comprises an endoscope having a proximal end and a distal end having a magnetic body. An imaging device transmits an image, associated with the distal end of the endoscope, to a display. A magnetic field generating apparatus generates a magnetic field to move the magnetic body and thus the distal end of the endoscope. A controller, coordinated with the display, controls the magnetic field generating apparatus to apply a magnetic field to change the position of the magnetic body and thus the position of the distal end of the endoscope. The controller controls the magnetic field generating apparatus to apply a magnetic field of a specific direction to change the orientation of the magnetic body and thus the orientation of the distal end of the endoscope.

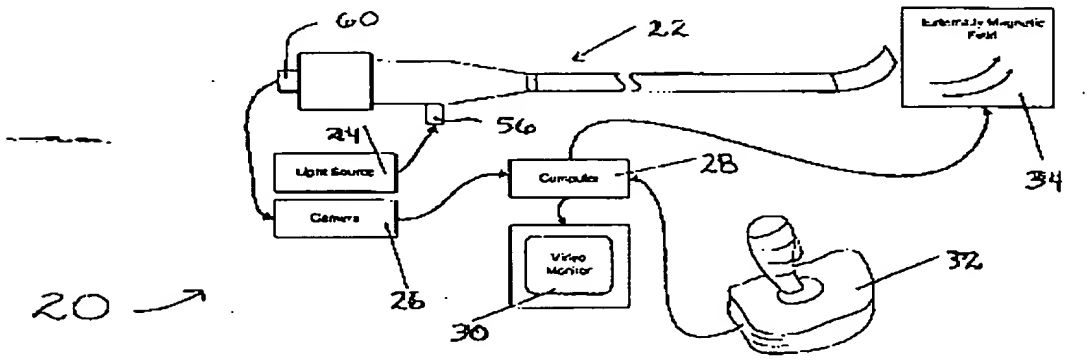


FIG. 1

Thus, in contrast to conventional uses of a magnetic ***gradient*** to "pull" a magnetic object in a particular direction, the present invention generates a magnetic ***field*** with which a magnetic object tends to align. Moreover, the controller for controlling the magnetic field generating apparatus is coordinated with the display from the imaging g system of the endoscope. Thus, a physician viewing the display can intuitively move the distal end of the endoscope based upon the image displayed.

The magnetic field generating apparatus can also generate a magnetic gradient, which can be used to move the distal end of the endoscope in addition to the field, but the system uses the direction of the applied magnetic field to orient the distal end of the endoscope.

The controller (32) is operable in at least two mutually perpendicular directions which causes the magnetic field generating apparatus to change the magnetic field to move the distal end of the endoscope in two mutually perpendicular directions. The display preferably includes indicia indicating an orientation of the displayed image. Movement of the controller in the first direction causes the magnetic field generating apparatus to change the magnetic field to move the distal end of the endoscope in a first plane indicated in a first direction relative to the indicia, and movement of the controller in the second direction causes the magnetic field generating apparatus to change the magnetic field to move the distal end of the endoscope in a second plane, perpendicular to the first plane, indicated in a second direction relative to the indication and perpendicular to the first indicia. This indicia may include at least one marker (70)

aligned with the first direction and at least one marker (70) aligned with the second direction.

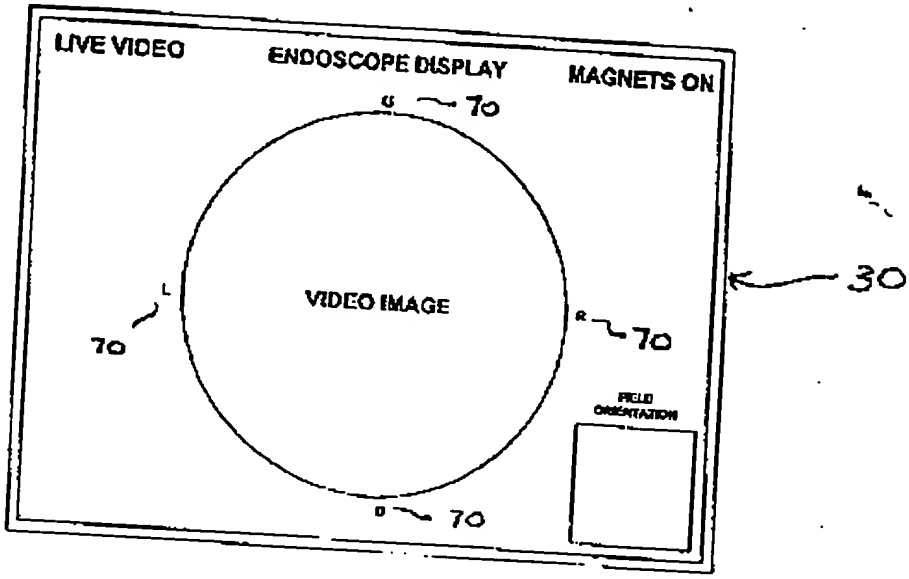


FIG 9

The display preferably has vertical and horizontal directions, and movement of the controller in one of the mutually perpendicular directions causes the magnetic field generating apparatus to change the magnetic field to move the distal end of the endoscope in the vertical direction as displayed on the display, and movement of the controller in the other of the mutually perpendicular direction causes the magnetic field generating apparatus to change the magnetic field to move the distal end of the endoscope in the horizontal direction as displayed on the display.

The system includes a signal processor that orients the image on the display so that the vertically "up" direction of the image is oriented at the top of the display regardless of the actual orientation of the axis of the endoscope.

The system preferably includes a controller for controlling the magnetic field generating apparatus to selectively apply a magnetic field to change the position of the magnetic body and thus the position of the distal end of the endoscope. The controller operable in at least two mutually perpendicular directions. Movement of the controller in one of the mutually perpendicular directions causes the magnetic field generating apparatus to change the magnetic field direction to change the orientation of the distal end of the endoscope in the vertical direction as displayed on the display, and movement of the controller in the other of the mutually perpendicular direction causes the magnetic field generating apparatus to change the magnetic field direction to change the orientation of the distal end of the endoscope in the horizontal direction as displayed on the display.

The method of the present invention comprises displaying an image from the distal end of the endoscope on a display that includes orientation indicia. The controller is operated to control the application of a magnetic field to the distal end of the endoscope. The controller is operable in at least two mutually perpendicular directions. Movement of the controller in one of the mutually perpendicular directions causes the magnetic field generating apparatus to apply a magnetic field direction to change the orientation of the distal end of the endoscope in a first plane corresponding to a first direction relative to the orientation indicia on the display. For example moving the controller forward and back pans the displayed image down and up respectively. Similarly movement of the controller in the other of the mutually perpendicular directions

causes the magnetic field generating apparatus to change the magnetic field direction to change the orientation of the distal end of the endoscope in a second plane, perpendicular to the first plane, corresponding to a second direction relative to the orientation indicia on the display, perpendicular to the first direction. Moving the controller left and right pans the image left and right.

Issues (37 C.F.R. §1.192(c)(6))

Is the invention as set forth in Claims 2, 4, 7, 9, and 10 sufficiently definite under 35 U.S.C. §112?

Is the invention set forth in Claims 2-4, 6-9, and 11-17 anticipated by Ueda et al., U.S. Patent No. 5,681,260.

Is the invention as set forth in Claim 5 non-obvious in view of Ueda et al., U.S. Patent No. 5,681,260, and Hibino et al., U.S. Patent No. 5,060,632?

Is the invention as set forth in Claim 10 non-obvious in view of Ueda et al., U.S. Patent No. 5,681,260, and Koninckx, U.S. Patent No. 5,899,851?

Grouping of Claims (37 C.F.R. §1.192(c)(7))

All the claims do not stand together. Claims 2, 3, 4, 5, 6, 7, 8, 9, 15, 16 and 17 are separately patentable.

Argument (37 C.F.R. §1.192(c)(8))

CLAIMS 2, 4,7, 9 AND 10 ARE
SUFFICIENTLY DEFINITE UNDER 35 U.S.C. §112.

Claim 2 recites a "display component" in line 4, and references the "display" in line 7. This is a clear an unmistakable reference to the display on the display component. There is nothing unclear or ambiguous to a person of ordinary skill in the art, and for at

least this reason, the rejection of claims 2, 4, 7, 9, and 10 under 35 U.S.C. §112 should be reversed.

CLAIMS 2-4, 6-9 AND 11-17 ARE NOT ANTICIPATED BY UEDA ET AL., U.S. PATENT NO. 5,681,260

Claim 2 (and claims 3, 6-9, and 11-14 which depend therefrom, and independent claim 4) requires a controller "controlling the magnetic field generating apparatus to apply a magnetic field of a specific direction to change the orientation of the magnetic body and thus the orientation of the distal end of the endoscope". Ueda et al. does not teach a controller that operates a magnet to apply an aligning field to align the distal end of an endoscope in a particular direction. Instead, Ueda et al. relies upon a magnetic gradient or pulling force to pull a magnet in a particular direction. Ueda et al. describes at least 31 different ways in which to use a magnetic gradient or pulling force to move a device in the body. At least 288 times Ueda et al. references this "pulling force" of the magnets.

Ueda lacks any appreciation of controlling the direction of a device in the body by aligning the device with an applied magnetic field. Instead, every embodiment of Ueda et al. relies upon the attractive force between the north and south poles of magnets to control a magnetic element. Thus, there is no attempt in Ueda to control the direction of the magnetic field being applied, or to even know the what the magnetic field direction is. Ueda et al. simply applies a magnetic gradient, irrespective of magnetic field direction, to pull a device to a desired position.

There is no way to control the magnetic field direction in any of the embodiments of Ueda et al., let alone a controller to apply a magnetic field of a specific direction to change

the orientation of the magnetic body and thus the orientation of the distal end of the endoscope. The magnetic field direction is simply not relevant to Ueda et al.

Ueda et al. does not teach or make obvious a magnetically navigable endoscope system with a controller "controlling the magnetic field generating apparatus to apply a magnetic field of a specific direction to change the orientation of the magnetic body and thus the orientation of the distal end of the endoscope" as required in claim 2; an endoscope system with a controller "causing the magnetic field generating apparatus to change the magnetic field direction to change the orientation of the distal end of the endoscope" as required in claim 15; a method of magnetically navigating an endoscope comprising operating a controller to control the application of a magnetic field to the distal end of the endoscope by causing the magnetic field generating apparatus "to apply a magnetic field direction to change the orientation of the distal end of the endoscope" as required in claim 16; or a method of magnetically navigating an endoscope by causing the magnetic field generating apparatus "to change the magnetic field direction to change the orientation of the distal end of the endoscope" as required in claim 17.

Ueda et al. clearly lacks the controller required by the claims 2 - 4, 6 – 9, and 11 – 17, and thus cannot anticipate these claims. Moreover, being completely devoid of any appreciation of the use of magnetic field direction for orienting a device, or any way to control magnetic field direction, Ueda et al. cannot make the invention as set forth in these claims obvious.

Claim 3 is directed to magnetically navigable endoscope system in which a controller controls a magnetic field generating apparatus to control the magnetic field and magnetic gradient generated by the apparatus. Ueda et al. discloses the use of a

magnetic gradient to control an endoscope. Ueda et al. does not teach the use of magnetic field alone or in combination with the magnetic gradient, to control an endoscope.

Claim 4 is even more clear, it requires a controller to apply "a magnetic field of a specific direction to change the orientation of the magnetic body" and to apply "a magnetic gradient to move the magnetic body thus the orientation and location of the distal end of the endoscope." Ueda et al. employs a gradient alone, and does not also use an aligning magnetic field as required in claim 4.

Claim 6 (and claims 7, 8 and 9 which depend from claim 6) is directed to magnetically navigable endoscope system according to claim 2 wherein the controller is operable in at least two mutually perpendicular directions, movement in which causes the magnetic field generating apparatus to change the magnetic field to move the distal end of the endoscope in two mutually perpendicular directions. Ueda et al. does not teach such a controller for changing the direction of a magnetic field applied by a magnetic field generating apparatus.

Claim 7 (and claim 8 which depends from claim 7) is directed to an endoscope system which include indicia indicating an orientation of the displayed image, and movement of the controller in a first direction causes the endoscope to move in a first plane indicated in a first direction relative to the indicia, and movement of the controller in a second direction causes the endoscope in a second plane, perpendicular to the first plane, indicated in a second direction relative to the indication and perpendicular to the first indicia.

Claim 8 further requires that the indicia include at least one marker aligned with the first direction and at least one marker aligned with the second direction. Ueda lacks any indicia, let alone indicia required by claim 8.

Claim 9 is directed to an endoscope system with a display, in which the display is coordinated with the controller so that movement of the controller in first and second mutually perpendicular directions causes the endoscope to move in the vertical and horizontal directions as shown on the display. As an endoscope system twists and turns in the body, the true orientation of the "up" gets confused. However in part because the controller does not mechanically operate the distal end of the endoscope, it is possible to coordinate the orientation of the displayed image with predetermined controller directions, so that movement of the controller in selected directions, causes predictable movement relative to the displayed image. This is not shown or suggested in Ueda et al.

Claim 15 is directed to a magnetically navigable endoscope system. Claim 15 requires a controller "operable in at least two mutually perpendicular directions." Movement of the controller in one of the mutually perpendicular directions causing the magnetic field generating apparatus to change the magnetic field direction to change the orientation of the distal end of the endoscope in the vertical direction as displayed on the display. Movement of the controller in the other of the mutually perpendicular direction "causes the magnetic field generating apparatus to change the magnetic field direction to change the orientation of the distal end of the endoscope in the horizontal direction as displayed on the display." This coordination with the displayed images is not shown in Ueda et al.. Ueda et al. is not concerned with or capable of manipulating magnet fields to achieve this function.

Claim 16 is directed to a method of magnetically navigating an endoscope. Claim 16 requires displaying an image from the distal end of the endoscope on a display with "orientation indicia." A controller, operable in at least two mutually perpendicular directions, is used to control the application of a regular field to the distal end of the endoscope. Movement of the controller in one of the mutually perpendicular directions causing the magnetic field generating apparatus to apply a magnetic field direction to change the orientation of the distal end of the endoscope in a first plane corresponding to a first direction relative to the orientation indicia on the display. Movement of the controller in the other of the mutually perpendicular directions causes the magnetic field generating apparatus to change the magnetic field direction to change the orientation of the distal end of the endoscope in a second plane, perpendicular to the first plane, corresponding to a second direction relative to the orientation indicia on the display, perpendicular to the first direction. This relation between the viewed image and a controller which changes the magnetic field direction, is not shown or suggested in Ueda et al.

Claim 17 is directed to a method of magnetically navigating an endoscope. Claim 17 requires operating a controller to control the application of a magnetic field to the distal end of the endoscope. The controller being operable in at least two mutually perpendicular directions. Movement of the controller in one of the mutually perpendicular directions causing the magnetic field generating apparatus to change the magnetic field direction to change the orientation of the distal end of the endoscope in the vertical direction as displayed on the display. Movement of the controller in the other of the mutual perpendicular directions causes the magnetic field generating apparatus to

change the magnetic field direction to change the orientation of the distal end of the endoscope in the horizontal direction as displayed on the display. This relation between the viewed image and the controller, and the use of a magnetic field direction is not shown in Ueda et al.

CLAIM 5 WOULD NOT HAVE BEEN OBVIOUS
FROM UEDA ET AL., U.S. PATENT NO. 5,681,260
IN VIEW OF HIBINO ET AL., U.S. PATENT NO. 5,060,632

Claim 5 depends from claim 2, and is allowable for at least that reason. However, claim 5 further requires a controller on the endoscope, adjacent the proximal end. There is no teaching or suggestion in Hibino of a controller on an endoscope to control the magnetic field generating apparatus to apply a magnetic field of a specific direction to change the orientation of the magnetic body and thus the orientation of the distal end of the endoscope. There is nothing in either Ueda et al., or Hibino et al. that discloses or suggests such a controller, let alone positioning such a controller directly on the endoscope.

It is inventive to provide a controller on the endoscope that does not actually control the endoscope directly, but which controls a magnetic field generating apparatus to control the endoscope.

Lacking any teaching of the use of magnetic field direction to control an endoscope, a controller for a magnetic field generating apparatus, or the placement of the controller for a magnetic field generating apparatus on an endoscope, Ueda et al. and Hibino et al. do not make the claimed invention obvious.

For this reason, the rejection of claim 5 should be reversed.

CLAIM 10 WOULD NOT HAVE BEEN OBVIOUS
FROM UEDA ET AL., U.S. PATENT NO. 5,681,260
IN VIEW OF KONINCKX, U.S. PATENT NO. 5,899,851

Claim 10 depends from claim 9, which applicant submits is allowable, and therefore claim 10 is allowable for the same reasons advanced with respect to claim 9. Furthermore, claim 10 is directed to a magnetically navigable endoscope system including a signal processor orienting the image on the display so that the vertically "up" direction of the image is oriented at the top of the display regardless of the actual orientation of the axis of the endoscope. This is not shown or suggested in Ueda et al. or Konickx. Ueda et al. lacks any teaching regarding the orientation of the displayed image.

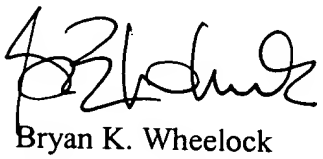
CONCLUSION

There is difference between a magnetic gradient, which applies and attractive or repulsive force on a magnetic object, and a magnetic field which acts in a particular direction, and which applicant's have discovered can be used to orient the distal end of a device such as an endoscope in a particular direction. In the front of a conventional permanent magnet, the direction of the magnetic field and the direction of the magnetic gradient are parallel, while at the side of a conventional permanent magnet, direction of the magnetic field is perpendicular to the direction of the gradient (i.e. the magnetic field will cause another object to align in a direction parallel to the face of the magnet, while the gradient still tries to pull the object toward the magnet. There is a significant difference between the use of a magnet gradient to pull an endoscope into an particular orientation, and the use of a magnetic field to cause the endoscope to turn essentially in

place. The use of the magnetic field to orient the endoscope facilitates smooth and continuous movement of the endoscope and the images from the endoscope.

For at least the foregoing reasons, the rejection of claims 2-17 should be reversed.

Respectfully submitted,



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Harness, Dickey & Pierce, P.L.C

APPENDIX

TEXT OF CLAIMS ON APPEAL

2. A magnetically navigable endoscope system comprising:

an endoscope having a proximal end and a distal end, the distal end having a magnetic body;

an imaging device which transmits an image, associated with the distal end;

a display component for displaying the image;

a magnetic field generating apparatus for generating a magnetic field to move the magnetic body and thus the distal end of the endoscope;

a controller coordinated with the display for controlling the magnetic field generating apparatus to apply a magnetic field to change the position of the magnetic body and thus the position of the distal end of the endoscope, the controller controlling the magnetic field generating apparatus to apply a magnetic field of a specific direction to change the orientation of the magnetic body and thus the orientation of the distal end of the endoscope.

3. The magnetically navigable endoscope system according to claim 2 wherein the controller controls the magnetic field generating apparatus to apply a magnetic

gradient to move the magnetic body and thus the location of the distal end of the endoscope.

4. A magnetically navigable endoscope system comprising:

an endoscope having a proximal end and a distal end, the distal end having a magnetic body;

an imaging device which transmits an image, associated with the distal end;

a display component for displaying the image;

a magnetic field generating apparatus for generating a magnetic field to move the magnetic body and thus the distal end of the endoscope;

a controller coordinated with the display for controlling the magnetic field generating apparatus to apply a magnetic field to change the position of the magnetic body and thus the position of the distal end of the endoscope, the controller controlling the magnetic field generating apparatus to apply a magnetic field and a magnetic gradient to apply a magnetic field of a specific direction to change the orientation of the magnetic body and to apply a magnetic gradient to move the magnetic body and thus the orientation and location of the distal end of the endoscope.

5. (Amended) The magnetically navigable endoscope system according to claim 2 wherein the controller is on the endoscope, adjacent the proximal end.

6. The magnetically navigable endoscope system according to claim 2 wherein the controller is operable in at least two mutually perpendicular directions, movement in which causes the magnetic field generating apparatus to change the magnetic field to move the distal end of the endoscope in two mutually perpendicular directions.

7. The magnetically navigable endoscope system according to claim 6 wherein the display includes indicia indicating an orientation of the displayed image, and wherein the controller is operable in at least two mutually perpendicular directions, and movement in the first direction causes the magnetic field generating apparatus to change the magnetic field to move the distal end of the endoscope in a first plane indicated in a first direction relative to the indicia, and movement in the second direction causes the magnetic field generating apparatus to change the magnetic field to move the distal end of the endoscope in a second plane, perpendicular to the first plane, indicated in a second direction relative to the indication and perpendicular to the first indicia.

8. The magnetically navigable endoscope system according to claim 7 wherein the indicia include at least one marker aligned with the first direction and at least one marker aligned with the second direction.

9. The magnetically navigable endoscope system according to claim 6, wherein the display has vertical and horizontal directions, and wherein the movement of the controller in one of the mutually perpendicular directions causes the magnetic field generating apparatus to change the magnetic field to move the distal end of the endoscope in the vertical direction as displayed on the display, and wherein the movement of the controller in the other of the mutually perpendicular direction causes the magnetic field generating apparatus to change the magnetic field to move the distal end of the endoscope in the horizontal direction as displayed on the display.

10. The magnetically navigable endoscope system according to claim 9 further comprising a signal processor orienting the image on the display so that the

vertically "up" direction of the image is oriented at the top of the display regardless of the actual orientation of the axis of the endoscope.

11. The magnetically navigable endoscope system according to claim 2 wherein there is a magnet channel in the distal end of the endoscope, containing the magnetic body.

12. The magnetically navigable endoscope system according to claim 2 wherein the distal end of the endoscope has a plurality of magnetic bodies.

13. The magnet assembly according to claim 2 wherein the magnetic body comprises a permanent magnetic material.

14. The magnet assembly according to claim 2 wherein the magnetic comprises a permeable magnetic material.

15. A magnetically navigable endoscope system comprising:

an endoscope having a proximal end and a distal end, the distal end having a magnetic body;

a component which transmits an image, associated with the distal end;

a two-dimensional display for displaying the image from the image-transmitting component, the display having a vertical and horizontal direction;

a magnetic field generating apparatus for generating a magnetic field to orient the magnetic body and thus the distal end of the endoscope;

a controller for controlling the magnetic field generating apparatus to selectively apply a magnetic field to change the position of the magnetic body and thus the position

of the distal end of the endoscope, the controller operable in at least two mutually perpendicular directions, movement of the controller in one of the mutually perpendicular directions causing the magnetic field generating apparatus to change the magnetic field direction to change the orientation of the distal end of the endoscope in the vertical direction as displayed on the display, and wherein the movement of the controller in the other of the mutually perpendicular direction causes the magnetic field generating apparatus to change the magnetic field direction to change the orientation of the distal end of the endoscope in the horizontal direction as displayed on the display.

16. A method of magnetically navigating an endoscope, the method comprising

displaying an image from the distal end of the endoscope on a display, the display including an orientation indicia; and

operating a controller to control the application of a magnetic field to the distal end of the endoscope, the controller being operable in at least two mutually perpendicular directions, movement of the controller in one of the mutually perpendicular directions causing the magnetic field generating apparatus to apply a magnetic field direction to change the orientation of the distal end of the endoscope in a first plane corresponding to a first direction relative to the orientation indicia on the display, and wherein the movement of the controller in the other of the mutually perpendicular directions causes the magnetic field generating apparatus to change the magnetic field direction to change the orientation of the distal end of the endoscope in a second plane, perpendicular to the first plane, corresponding to a second direction relative to the orientation indicia on the display, perpendicular to the first direction.

17. A method of magnetically navigating an endoscope, the method comprising:

displaying an image from the distal end of the endoscope on a display;

operating a controller to control the application of a magnetic field to the distal end of the endoscope, the controller being operable in at least two mutually perpendicular directions, movement of the controller in one of the mutually perpendicular directions causing the magnetic field generating apparatus to change the magnetic field direction to change the orientation of the distal end of the endoscope in the vertical direction as displayed on the display, and wherein the movement of the controller in the other of the mutual perpendicular directions causes the magnetic field generating apparatus to change the magnetic field direction to change the orientation of the distal end of the endoscope in the horizontal direction as displayed on the display.